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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/669,833	09/26/2000	Linda S. Mansfield	MSU 4.1-528	2531

21036 7590 07/15/2003

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EXAMINER	
BASKAR, PADMAVATHI	

ART UNIT	PAPER NUMBER
1645	12

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/669,833	MANSFIELD ET AL	
	Examiner	Art Unit	
	Padmavathi v Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29 and 30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/8/03 has been entered.

2. Applicant's amendment filed on 4/8/03 is acknowledged. Claims 29 and 30 have been amended. Claims 32-35 have been canceled. Claims 29 and 30 are pending the application.

Claim Rejections - 35 USC 112, second paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 29 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 29 is rejected as being vague and indefinite for the recitation of " (+/4) 16KD antigen and (+/- 4) 30 KD antigen. Does applicant intend to mean 16KD (+/- 4) and 30 KD (+/- 4) antigen?

Claim Rejections - 35 USC 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter

sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negative by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liang et al 1998 (Infection and Immunity; 66 (5) 1834-1838) or Marsh et al 1996 (JAVMA, 209: 1907-1913) in view of Harlow and Lane 1988 (Antibodies; Cold Spring Harbor).

Liang et al 1998 teach antibodies to 16KD antigen and 30KD antigen of S.neurona (see figure 1 and page 1835, right column, first paragraph, figure 3 B),

Marsh et al 1996 (JAVMA, 209: 1907-1913) teaches antibodies to immunodominant protein, approximately 29KD from S.neurona merozoites (see page 1910, left column and figure 3). However, the Prior art does not teach a method of producing antibodies against S.neurona proteins 16KD antigen and 30KD antigen.

It is well known and routine in the art of immunology methods of producing monoclonal antibodies and polyclonal antibodies against antigens, (Harlow and Lane chapter 6 and 5 respectively, 1988). The prior art teaches a method of producing antibodies by immunizing mice with antigen and adjuvant (see pages122, 123, 102,103, 106 from chapter 5). Further the

prior art teaches a method of producing hyper-immune sera (see page 115 from chapter 5). Samples of blood were collected and serum-containing antibodies were isolated as described in page 119 from chapter 5 for checking the production of specific antibodies (page 116 from chapter 5).

The prior art also teaches method of producing monoclonal antibodies by immunizing mice with antigen and adjuvant (see page 148 from chapter 6) and spleen cells were removed and fused with myeloma cells. Fused cells were screened for the production of monoclonal antibodies (figures 6.1, 6.2, 6.3 and pages 148, 202, 217-219 from chapter 6)

Liang 1998 clearly suggests that antibodies to Sn 16 of S.neurona antigen, which may be useful in vaccine preparation, and merozoites, which are potential targets for specific antibodies (see abstract). Further, the prior art suggests S.neurona infection of the horses induce antibodies to Sn 16 KD indicating that these proteins are strong immunogens and specific antibodies may lyse the merozoites via complement, inhibit their infection (see Discussion). Thus the prior art suggests antibodies to 16KD antigen are important in neutralizing merozoites.

Marsh et al teach serum obtained from horses infected with Neospora gave false positive reaction on the western blot assay for S.neurona (see page 1912, right column, top paragraph) immunodominant antigen approximately 29KD antigen. The prior art suggests that it is important to produce antibodies specific to S.neurona immunodominant protein such as 30kD to avoid false positive results. Therefore, it would be obvious to one of ordinary skill in the art to produce specific antibodies to immunodominant protein 16KD and 30kD antigen from S.neurona merozoites. Further it is routine in the immunology art to produce monoclonal or polyclonal antibodies for use sensitive assays such as ELISA for specific diagnosis of infection or treating or preventing the parasitic infections with specific antibodies.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to raise monoclonal or polyclonal antibodies to different potent surface antigens such as 16KD or 30KD which could be used in diagnostics or to treat infection with a reasonable expectation of success because it would help to treat or cure or diagnose the infection in horses as suggested by Liang et al et al or Marsh et al. An artisan of ordinary skill would have been motivated in applying the art disclosed by the prior art Liang or Marsh et al 1998 to Harlow and Lane to prepare antibodies to surface proteins because Liang et al suggests that protective humoral immunity to S.neurona infection is important. The claimed invention is prima facie obvious over Liang et al or Marsh et al each in view of Harlow and Lane 1986 absent any convincing evidence to the contrary.

Status of Claims

7. Claims 29-30 are rejected

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

7/8/03

LYNETTE R. F. SMITH
SUPERVISORY PATENT
TECHNOLOGY CENTER